

**TINFU ISOPROPYL ALCOHOL PREP PADS- isopropyl alcohol cloth**  
**Shandong T&F Nonwoven Co., Ltd**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Isopropyl Alcohol, 70% v/v

**Purpose**

Antiseptic

**Use**

For preparation of the skin prior to injection.

**Warnings**

For external use only. Flammable, keep away from fire or flame.

**Do not use**

- with electrocautery procedures.

When using this product do not get into eyes. do not apply over large areas of the body. in case of deep or puncture wounds, animal bites or serious burns, consult a doctor. use only in a well ventilated area.

Stop use and ask a doctor if irritation and redness develops.

If pregnant or breastfeeding ask a health professional before use.

Keep out of reach of children. If accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply to skin as needed.
- Discard after single use.

**Other information**

- Store at room temperature 15-30C (59-86F)

**Inactive ingredients**

Water

Package Label - Principal Display Panel

NDC: 82167-000



TINFU ISOPROPYL ALCOHOL PREP PADS

isopropyl alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82167-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82167-000-01	0.12 mL in 1 PATCH; Type 0: Not a Combination Product	08/25/2021	
2	NDC:82167-000-02	100 in 1 BOX	08/25/2021	
2		0.12 mL in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:82167-000-03	200 in 1 BOX	08/25/2021	
3		0.12 mL in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:82167-000-04	300 in 1 BOX	08/25/2021	
4		0.12 mL in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:82167-000-05	0.25 mL in 1 PATCH; Type 0: Not a Combination Product	08/25/2021	
6	NDC:82167-000-06	100 in 1 BOX	08/25/2021	
6		0.25 mL in 1 PACKET; Type 0: Not a Combination Product		
7	NDC:82167-000-07	200 in 1 BOX	08/25/2021	
7		0.25 mL in 1 PACKET; Type 0: Not a Combination Product		
8	NDC:82167-000-08	300 in 1 BOX	08/25/2021	
8		0.25 mL in 1 PACKET; Type 0: Not a Combination Product		
9	NDC:82167-000-09	0.56 mL in 1 PATCH; Type 0: Not a Combination Product	08/25/2021	
10	NDC:82167-000-10	100 in 1 BOX	08/25/2021	
10		0.56 mL in 1 PACKET; Type 0: Not a Combination Product		
11	NDC:82167-000-11	200 in 1 BOX	08/25/2021	
11		0.56 mL in 1 PACKET; Type 0: Not a Combination Product		
12	NDC:82167-000-12	300 in 1 BOX	08/25/2021	
12		0.56 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/25/2021	

Labeler - Shandong T&F Nonwoven Co., Ltd (541535862)

Establishment

Name	Address	ID/FEI	Business Operations
Shandong T&F Nonwoven Co., Ltd.		541535862	manufacture(82167-000)

Revised: 8/2021

Shandong T&F Nonwoven Co.,  
Ltd